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EXAMINER	
JOHNSON, JERROLD D	

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3728	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	10/668,629	DELANEY ET AL.	
	Examiner	Art Unit	
	Jerrold Johnson	3728	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Jerrold Johnson*. (3)_____.

(2) *Pat Fay*. (4)_____.

Date of Interview: *22 January 2008*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: *proposed amended claims 1-23, attached herewith*.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *see attached*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

_____
Examiner's signature, if required

Interview Summary

Mr. Patrick Fay, the Applicant's representative and Mr. Jerrold Johnson, the Examiner of record on the case agree that proposed amended claims 1-23, which were worked on by both Mr. Fay and Mr. Johnson, are allowable over the prior art of record. The Examiner understands that the proposed claims will be submitted with and RCE.

The Examiner's position with respect to the allowability of the proposed is as follows:

With respect to Ullman US 6,569,106:
Firstly, the Examiner recognizes that the Applicant does not believe that the embodiment shown in Fig. 4 of Ullman discloses what could reasonably be identified as a "sheath" or a "tubular enclosure" or a "lumen." The Examiner has endeavored to interpret these three claim limitations in a reasonable manner as is required. The dictionary definitions of "sheath" and "lumen" are provided below. The Examiner, however, also recognizes that the arguments previously presented by the Applicant in response to the Examiner's interpretation of these claim limitations and his identification of the corresponding elements in Ullman are also well reasoned. The Examiner submits that the claim amendments newly proposed by the Applicant in response to the Examiner's suggestions, clearly define over the reference of Ullman, despite the fact that the Examiner and the Applicant do not agree on the Examiner's interpretation of these claim limitations and the Examiner's identification of the corresponding elements in Ullman.

Specifically, all of the claims are now directed at a packaging for a catheter. Ullman in col. 3, lines 29-30 does suggest that his invention has applicability to catheters with some modification, but does not elaborate on this suggestion. Other than this single sentence, the disclosure of Ullman is specifically directed at guide wires, not at

catheters. Additionally, Ullman is not designed such that the first and second ends of his "sheath" are adapted to receive the distal and proximal ends of the catheter. Ullman's "sheath" includes a second end (the funnel 18) that is not adapted to receive the proximal end of a device, as the proximal end of the device is not intended to be inserted into his device to an extent where the second end is disposed within the funnel 18. See col. 2, lines 60-62. Additionally, the hydration opening of Ullman 30 is not capable of directing a flow stream toward the first and second ends of the sheath, as the intended use of the hydration opening 30 of Ullman is as a filling port for the housing 11. If the hydration opening 30 of Ullman did direct a flow to the second end of the sheath, the flushing fluid inserted into the hydration opening would spill out the second end of the sheath (the funnel) presumably onto the floor. That scenario is pretty unlikely. Additionally, the hydration opening 30 is not near the middle of his "sheath", but is instead proximate to the second end of the sheath (again the funnel 18). Finally, the size relationship of the "lumen" of Ullman to the device for which it is designed (a guide wire) is inconsistent with the claim limitation. Fig. 5 shows this size relationship. The "lumen" is not slightly larger than the guide wire, but is many times larger. Were Ullman used for catheters, as the reference suggests, one would imagine that this same size relationship would be maintained. Accordingly, the claims now define quite clearly over Ullman in a very large number of ways.

With respect to Samuels US 6,588,588, this reference to Samuels is not directed to catheters, nor could it be said that it inherently is capable of being used for that purpose. Although the element 50 does have first and second ends 44 and 48, the circular loop packaging of Samuels, once assembled does not have first and second ends. Clearly, Samuels does not disclose first and second ends that are adapted to receive the distal and proximal ends of a catheter. The hydration opening 12 of Samuels is not near a middle of the sheath, as it is within his circular loop that does not have a "middle." Similarly, the hydration opening 12 is proximate the first and second ends 44,48 of the tubular portion 50, but not the middle of tubular portion 50 of the

packaging. Finally, Samuels does not show a hydration opening 12 that directs first and second flow streams to the first and second ends respectively as is claimed. Accordingly, the claims clearly define over Samuels '588 in a number of ways.

With respect to Samuels US 6,375,006, this other reference to Samuels is also not directed to catheters, nor could it be said that it inherently is capable of being used for that purpose. The ends of the sheath are not adapted to receive the distal and proximal ends of a catheter. The hydration opening 432 is not near the middle of the sheath, nor would flushing fluid be directed to the first and second ends of the sheath, as claimed. The size relationship of the lumen to the guide wires is also different from what is claimed. Accordingly, the claims clearly define over Samuels '006 in a number of ways.

With respect to Colliver US 5,427,114, this reference does not show a protective package for a catheter, nor does it show a device that removably protects a catheter before use. The internal catheter 30 is not removable from the outer casing 24. These two elements 30,24 are inseparable and are used simultaneously. The hydration opening 14 does not direct first and second streams to the first and second ends of the sheath as claimed, but is instead disposed to direct a single stream to the perforations 26 proximate the end 28. Accordingly, the claims clearly define over Colliver in a number of ways.

With respect to Taniguchi US 3,861,395, Taniguchi discloses a hydration opening (beneath the reservoir 32) for administering lubricant to the catheter at the time the catheter is inserted into the body. The location of the hydration opening is not near the middle of the sheath, but is instead immediately adjacent an end of the sheath. The hydration opening also does not direct a stream toward both ends of the sheath, but instead directs a steam directly downward on the portion of the catheter that will be immediately inserted into the body. The size relationship of the sheath to the catheter is

also not as claimed. The lumen within the sheath of Taniguchi is disclosed being of a much larger size than that of the catheter. The claim sets forth that the lumen is just slightly larger than the catheter. Accordingly, the claims clearly define over Colliver in a number of ways.

Finally, with respect to Farrell et al. US 6,053,313, this reference discloses the common catheter packaging. The present invention is disclosed as being an improvement to this common arrangement in that the present invention provides a hydration opening through which a flushing fluid is introduced near the middle of the lumen of the sheath, within which the catheter is disposed. Flushing fluid is directed to both the first and second ends of the sheath to assist in the removal of the catheter from the lumen within the sheath.

The Examiner found no references that address the problem identified by the Applicant in the present application. None of the references relied upon by the Examiner suggest a hydration opening that would be used to modify the reference of Farrell in the manner claimed.

Taniguchi discloses a hydration opening for administering lubricant to the catheter at the time of insertion of the catheter into the body. The teachings of Taniguchi would not logically be applied to Farrell, but even if it were illogically applied, the resultant would not suggest what is claimed. Additionally, the hydration openings of Samuels 6,375,006 (element 432) and Ullman (element 30) would not logically be applied to Farrell. Samuels and Ullman disclose a different type of apparatus than Farrell. Specifically, the devices of Ullman and Samuels are not intended as shipping packaging, but instead are used to temporarily house guidewires during surgery. The hydration openings are not designed to direct flushing fluid to assist in the removal of the catheter from the sheath, but are instead used to maintain a fluid in the device to sterilize guidewires disposed

therein. Accordingly, there would be no logical reason to apply the teachings of Ullman and Samuels to the packaging of Farrell, but even if the teachings were illogically applied, the resultant would not render the claims unpatentable.

For at least the foregoing reasons, the claims are allowable over the prior art references of record, including those specifically set forth above.

Mickey Yu
Supervisory Patent Examiner
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FACSIMILE COVER SHEET

FAX NO : (571) 273-7141

TO : Commissioner for Patents
Attn: EXAMINER JERROLD D. JOHNSON

FROM : Patrick J. Fay, Esq. of Fay Kaplun & Marcin, LLP

DATE : January 22, 2008

SUBJECT : U.S. Patent Appln. Serial No. 10/668,629
for *Mid-Stream Flushing Adapter Assembly*
Our Ref.: 10123/03501

NUMBER OF PAGES INCLUDING COVER : 7

MESSAGE:

Examiner Johnson,

As per our telephone coversation, please see attached.

Thank you,

Patrick J. Fay

DRAFT

1. (Currently Amended) A protective package for ~~an elongated medical device~~ a catheter, comprising:

a protective sheath including a lumen sized to removably protect a catheter before use, the sheath having a length corresponding to a length of a catheter to be received therein and an inner diameter slightly greater than an outer diameter of a catheter to be received therein, ~~receive a body of the elongated medical device wherein~~ a first end of the sheath ~~is~~ being adapted to receive a distal end of ~~the elongated medical device~~ a catheter to be received therein and a second end of the sheath ~~is~~ being adapted to receive a proximal end of ~~the elongated medical device~~ a catheter to be received therein; and

a hydration opening into the lumen ~~disposed~~ between the first and second ends of the sheath so that a desired proportion of a flushing fluid introduced into the lumen near a middle of the sheath and so that a desired proportion of flow thereinto is directed toward the first and second ends of the sheath with a first flow stream extending from the hydration opening to the distal end of the catheter and a second flow stream extending from the hydration opening to the proximal end of the catheter.

2. (Currently Amended) The protective package according to claim 1, wherein the sheath is formed as a hoop ~~and wherein the medical device is a catheter~~.

3. (Previously Presented) The protective package according to claim 1, further comprising a protective assembly disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end of the catheter.

4. (Previously Presented) The protective package according to claim 1, further comprising a luer attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

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5. (Previously Presented) The protective package according to claim 1, further comprising an adapter coupled to the hydration opening for receiving a syringe.

6. (Currently Amended) The protective package according to claim 3, wherein the protective assembly is adapted to prevent damage to a curvature of the distal end of the ~~elongated medical device~~ catheter.

7. (Cancelled)

8. (Cancelled)

9. (Previously Presented) The protective package according to claim 1, wherein the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

10. (Previously Presented) The protective package according to claim 9, wherein the desired ratio is one to one.

11. (Previously Presented) The protective package according to claim 1, wherein the hydration opening is substantially equidistant from the first and second ends.

12. (Previously Presented) The protective package according to claim 1, wherein the hydration opening is oriented to direct an amount of flow toward the first end which is different than an amount of flow directed toward the second end.

13. (Previously Presented) The protective package according to claim 12, wherein the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

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14. (Previously Presented) The protective package according to claim 13, wherein the desired ratio is one to one.

15. (Currently Amended) A catheter kit comprising:

a catheter having a ~~shaped distal tip~~ distal end and a proximal end; and

a catheter packaging comprising:

a tubular enclosure removably protecting the catheter before use, the tubular enclosure having a length ~~and an inner diameter~~ corresponding ~~,respectively,~~ to a length ~~and outer diameter~~ of the catheter and an inner diameter defining a lumen that is slightly greater than an outer diameter of the catheter;, a first end of the tubular enclosure being adapted to receive the ~~shaped distal tip~~ distal end and; a second end of the tubular enclosure being adapted to receive ~~a~~ the proximal end of the catheter;; and

a hydration opening extending into ~~an interior of the tubular enclosure~~ the lumen between the first and second ends ~~thereof~~ of the tubular enclosure, the hydration opening being positioned so that a desired proportion of flow ~~thereinto~~ of a flushing fluid introduced into the lumen enters the lumen near a middle of the enclosure and is directed toward the first and second ends of the enclosure such that a first flow stream extends from the hydration opening to the distal end of the catheter and a second flow stream extends from the hydration opening to the proximal end of the catheter.

16. (Currently Amended) The catheter kit according to claim 15, further comprising a protective structure disposed at the first end, the protective structure maintaining a desired curvature of ~~the~~ a shaped distal tip of the catheter.

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17. (Previously Presented) The catheter kit according to claim 15, wherein the tubular enclosure is coiled to form a hoop.

18. (Previously Presented) The catheter kit according to claim 15, wherein a hydrating fluid introduced into the tubular enclosure via the hydration opening is divided such that the proximal end and the distal end of the catheter are substantially equally hydrated.

19. (Previously Presented) The catheter kit according to claim 15, wherein the catheter is a micro-catheter with a shaped distal tip.

20. (Previously Presented) The catheter kit according to claim 15, wherein the hydration opening is substantially equidistant between the first and second ends.

21. (Currently Amended) A protective package for removably receiving an elongated medical device, comprising:

a protective sheath including a lumen sized to tightly fit a body of the elongated medical device to be received therein, the sheath removably protecting the elongated medical device before use, a first end of the sheath being adapted to receive a distal end of the elongated medical device and a second end of the sheath being adapted to receive a proximal end of the elongated medical device, a length of the sheath corresponding to a length of the elongated medical device and an inner diameter of the lumen being slightly greater than an outer diameter of the elongated medical device; and

a hydration opening into the lumen ~~disposed~~ between the first and second ends of the sheath, the hydration opening being positioned so that a flushing fluid supplied to the hydration opening is supplied to the lumen near a middle of the sheath ~~sheath~~ with a desired proportion of flow thereinto being directed toward the first and second ends of the sheath such that a first flow stream extends from the hydration opening to the distal end of

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the elongated medical device and a second flow stream extends from the hydration opening to the proximal end of the elongated medical device.

22. (Currently Amended) A packaging method for a catheter comprising:

providing a catheter having a distal end and a proximal end;

providing a shipping packaging in the form of a tubular enclosure having a length corresponding to a length of the catheter and an inner diameter defining a lumen that is slightly greater than an outer diameter of the catheter;, a first end of the tubular enclosure being adapted to receive the distal end; a second end of the tubular enclosure being adapted to receive the proximal end of the catheter;

providing the tubular enclosure with a hydration opening extending into the lumen between the first and second ends of the tubular enclosure, the hydration opening being positioned so that a desired proportion of a flow of flushing fluid ~~may be~~ introduced into the lumen via the hydration opening enters the lumen near the middle of the catheter ~~and that a desired proportion of flow thereinto~~ is directed toward the first and second ends of the enclosure such that a first flow stream extends from the hydration opening to the distal end of the catheter and a second flow stream extends from the hydration opening to the proximal end of the catheter; and

removably inserting the catheter into the lumen of the tubular enclosure.

23. (Currently Amended) A catheter packaging comprising:

a tubular enclosure having a first end and a second end for removably protecting a catheter having a shaped distal tip and a proximal end, the tubular enclosure having a length corresponding to a length of the catheter and an inner diameter defining a lumen that is slightly greater than an outer diameter of the catheter; a first end of the tubular enclosure

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being adapted to receive the shaped distal tip distal end; a second end of the tubular enclosure being adapted to receive the proximal end of the catheter;

a hydration opening extending into the lumen between the first and second ends of the tubular enclosure, the hydration opening being positioned so that a desired proportion of a flow of a flushing fluid ~~may be~~ introduced into the lumen via the hydration opening enters the lumen near the middle of the tubular enclosure and ~~that a desired proportion of flow thereinto~~ is directed toward the first and second ends of the enclosure such that a first flow stream extends from the hydration opening to the distal end of the catheter and a second flow stream extends from the hydration opening to the proximal end of the catheter; and

an additional protective structure disposed at the first end of the tubular enclosure adapted to prevent crushing of the shaped distal tip.